UNITED STATES OF AMERICA
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 05-10403-DPW

LLOYD F. AUDETTE,
Plaintiff,

v.

UMASS CORRECTIONAL HEALTH,
A Commonwealth Medicine Program,
Defendant, and

DEPARTMENT OD CORRECTION,
Kathleen M. Dennehy, Commissioner
Defendant,

PLAINTIFF'S RESPONSE TO
UMASS CORRECTIONAL HEALTH'S
OPPOSITION TO PLAINTIFF' MOTION FOR
TEMPORARY RESTRAINING ORDER
AND REQUEST FOR HEARING

Now comes the Plaintiff Lloyd F. Audette in the above entitled action and hereby responds to the Defendant's response for Plaintiff's Motion for Temporary Restraining Order.

The Plaintiff states that his medical conditions have not been appropriately treated at all times, that Charlie Black knowingly lied in his statement to the Defendant's Attorney James A. Bello and that the defendant is deliberate to Plaintiff's medical needs and has now acted in retaliation to Plaintiff filing civil remedy.

RELEVANT FACTS

1. Plaintiff, pro-se inmate incarcerated at the S.B.C.C. facility agrees that defendant acknowledges he suffers from AIDS, Hepatitis C, Zollinger Ellison Syndrome, and multiple orthapedic injuries.

2. To date, Plaintiff now weighs 142 lbs. and is still losing weight.

3. The records will show that Plaintiff was receiving testosterone and oxandrolone prior to his incarceration due to AIDS waisting syndrome caused by a low CD4 count.

4. Plaintiff did see Dr. King and Defendant states that Dr. King negated in his duties to order proper footware.

5. Plaintiff is not responsible to provide his own medical treatment when incarcerated, even if he weren't indigent, which he is.

6. Health Service Administrator lied to Attorney James A. Bello in that SUSTIVA AND DDI are not Hepatitis C medications, they are AIDS medications and that SUSTIVA in fact blocks the absorbtion of methadone into the bloodstream decreasing its efficacy not the other way around as Charlie Black would have the court believe(see attached SUSTIVA literature)

7. Defendant's have used Retaliation tactics by stopping the plaintiff's methadone treatment and decreasing it by half, 20 mg. per day for the first two days and then 10 mg. per day then lower to zero knowing that this type of reduction will cause

severe withdrawals and put the Plaintiff's health at jeopardy.

PRELIMINARY INJUNCTION STANDARD

"The purpose of a preliminary injunction is to preserve the status quo so as to permit the trial court, upon full adjudication of the case's merits, more effectively to remedy discerned wrongs." CMM Cable Rep., Inc. v. Ocean Coast Properties, 48 F.3d 618,620 (1st Cir. 1995)(Citing Chalk v. United States Dist. Court. 840 F.2d 701,704(9th Cir. 1988); American hosp. Ass'n v. Harris, 625 F.2d 1328,1330 (7th Cir. 1980)). "The court's interim injunctive decree attempts to prevent further injury by maintaining the status quo, thus enhancing the court's ability, if it untimely finds for the movant, to minimize harmful effects of the defendant's wrongful conduct." Id (citation omitted).

A four part test must be taken into account to determine granting or denying a preliminary injunction, (1) the movant's likelihood of success on the merits, (2) the potential for irreparable injury, (3) a balancing of the relevant equities, and (4) the effect on the public interest.

PLAINTIFF'S LIKELIHOOD OF SUCCESS ON THE MERITS

Plaintiff claims stem from being disabled under the ADA which defines a disability as be a person with AIDS, arthritis, neuropathy, nerve damage etc. (disfigurement).

Definition under 42 USCA § 12102:

(2) Disability

The term disability means with respect to an individual-

(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual.

Further, the defendant's do not contest that the Plaintiff is disabled within the meaning of the statute. see Roth v. Lutheran General Hospital, 57 F.3d 1446,1454(7th Cir. 1995).

Plaintiff's likelihood of success depends on whether or not he can verify his claims for relief. Mass. Gen. Laws 111 § 72F states the meaning of Neglect:

Neglect, the failure to provide goods and services necessary to avoid physical harm.

Because of the very fact of incarceration, the Supreme Court has recognized that "[i]t is but just that the public be required to care for the prisoner, who cannot by reason of the deprivation of liberty, care for himself." Estelle v. Gamble, 429 U.S. 97 (1976)(citations omitted). Prison officials are more than merely negligent if they deliberately defy the express instructions of prison doctors. Martinez v. Mancusi, 443 F.2d 921,924 (2d Cir. 1970), Id at 104-05, 97 S.Ct. at 291, see also Kelly v. McGinnis, 899 F.2d 612; ("If [ ], deliberately interfered with his medically prescribed treatment for the purpose of causing him unnecessary pain,[ ], could be subject to liability even though he suffered no apparent injury, See e.g Gill v. Mooney, 824 F.2d 192 (2d Cir. 1987)

Prison officials denied Plaintiff both A.M and P.M. snacks on numerous occasions after the doctor's order was faxed, refaxed, and refaxed while Plaintiff continually lost body weight. see Affidavit attached hereto.

Plaintiff's Eighth Amendment claims are meritorious when "the evloving standards of decency that mark the progress of a maturing society." Trop v. Dulles, 78 S.CT at 598, see also Gregg v. Georgia, 428 U.S. 153 at 172-173(1976) Regardless of how evidenced, deliberate indifference to a prisoner's serious illness or injury state a cause of action under §1983, Estelle v. Gamble, 429 U.S. 97 (1976) or which involve "the unnecessary and wanton infliction of pain." Weems v. United States, 217 U.S. 349(1910) ("repeated examples of negligent act which disclose a pattern of conduct by the prison medical staff" can sufficiently evidence deliberate indifference, Kelly v. McGinnis, 899 F.2d 612 (C.A. 7(III)1990); Wellman 715 F.2d at 272 (quoting Ramos, 639 F.2d 559, 575 (10th Cir. 1980), cert denied 450 U.S. 1041 (1981)

When prison authorities deny reasonable requests for medical treatment, such denial exposes the inmate "to undue suffering or the threat of tangible residual injury." Westlake v. lucas, 537 F.2d 857,869 . Short of absolute denial "if medical treatment [i]s delayed for non-medical reasons, a case for deliberate indifference has been made out" Ancota v. Prison Health Servs., 769 F.2d 700; accord Archer v. Dutcher, 733 F.2d 14 (2d Cir.

1984)(allegation that emergency medical care to pregnant inmate was delayed in order to make her suffer states a claim of deliberate indifference under Estelle). Deliberate indifference is also evident where prison officials erect arbitrary and burdensome procedures that "result [] in interminable delays and outright denials of medical care to suffering inmates." Todaro v. Ward, 565 F.2d 48,53 (2d Cir. 1977). Prison officials may not, with deliberate indifference to the serious medical needs of the inmate, opt for "'an easier and less efficacious treatment'" of the inmates condition. West, 571 F.2d at 162 (citations omitted). Nor may they condition provision of needed medical services on the inmates ability or willingness to pay. See Ancata, 769 F.2d at 704; cf. City of Revere, 463 U.S. 239 (1983)(right to treatmentconstitutionally mandated regardless of who pays for treatment). Finally, deliberate indifference is demonstrated "[w]hen ... prison authorities prevent inmate from receiving recommended treatment for serious medical needs or deny access to physician capable of evaluating the need for such treatment." Inmates of Allegheny Jail v. Pierce, 612 F.2d 754,762 (3d Cir. 1979).

A medical need is "serious", in satisfaction of the second prong of the Estelle test, if it is "one that has been diagnosed by a physician as requiring treatment or one that a lay person would easily recognize the necessity for a doctor's attention." Pace v. Fauver, 479 F. Supp. 456,458 (D.N.J.1979), aff'd,

649 F.2d 860 (3d Cir. 1981); accord Laaman v. Helgemoe, 437 F. Supp 269,311(D.N.H.1977). The seriousness of an inmate's medical needs may also be determined by reference to the effect of denying the particular treatment. For instance, Estelle makes clear that if "unnecessary and wanton infliction of pain," 429 U.S. at 103, 97 S.Ct at 290, results as a consequence of denial or delay in the provision of adequate medical care, the medical need is of the serious nature contemplated by the eighth amendment. See id at 105, 97 S.Ct. at 291. In addition, where the denial or delay causes the inmate to suffer a lifelong handicap or permanent loss, the medical need is serious. See, e.g. Archer, 733 F.2d at 16 (pregnant inmate who miscarried stated cognizable claim where she claimed that defendants intentionally delayed emergency medical aid in order to make her suffer); Ramos v. Lamm, 639 F.2d 559,576(10th Cir. 1980) (delay in providing oral surgery resulted in "continued and unnecessary pain and loss of teeth"), cert. denied, 450 U.S. 1041(1981); Laaman, 437 F. Supp. at 312 (denial of treatment may result in permenant damage or require corrective surgery).

In the case at bar, the Plaintiff has been denied orthopedic footware because he is unable to pay for them. He has been denied follow up physical therapy for his left knee although is was ordered and it is now possible that he will need another orthoscopic surgery to correct the knee, an MRI needs to be ordered although it has not been. Plaintiff was denied proper

evaluation and treatment for a serious weight loss problem and had to wait over one year after constantly complaining about it to receive scheduling with the endocrine clinic. Plaintiff had to wait over one year to start Hepatitis C treatment after all tests and biopsies were completed. Plaintiff was dispensed six percosets per day for pain when the doctor ordered oxicodone because the plaintiff could not tollerate the tylenol in the percosets and when the mistake was discovered some six months later, Plaintiff was placed on methadone without the drug interactions being checked in advance. Plaintiff brought to the defendant's attention that SUSTIVA, an HIV(AIDS) medication caused the methadone not to absorb into the patients bloodstream.

Both SUSTIVA and VIRAMUNE are known as nonnucleoside reverse transcriptase inhibitors or (nonnukes). Viramune causes blood-based methadone levels to fall by an average of 29%, but the absorbtion rate as much as 70% in some HIV patients. The literature states that the methadone should be increased to prevent drug withdrawal symptoms (see exhibit).

Instead of increasing the methadone as recommended, the defendants arbitrarily are decreasing the doses at an unsafe rate to intentionally cause the plaintiff to suffer severe withdrawal symptoms as an act of retaliation against plaintiff. Methadone withdrawals can last up to several months depending on the dosage and length of time the patient was receiving methadone treatment.

In Johnson v. Summers, , 411 Mass 92 at 86 the standard of review is set forth as being whether the evidence in light most favorable to the plaintiff, "anywhere in the evidence, from whatever source derived, any combination of circumastance could be found from which a reasonable inference could be drawn in favor of the plaintiff." Miga v. Holyoke, 398 Mass. 343,348 (1986). Poirier v. Plymouth, 374 Mass. 206,212 (1978), quoting Raunela v. Hertz Corp., 361 Mass. 341,343 (1972).

A §1983 plaintiff must demonstrate that (1) a person acting under color of State law commited the conduct complained of and (2) the conduct deprived the plaintiff of a right, privilege or immunity secured by the Constitution or laws of the United States. Parratt v. Taylor, 451 U.S. 527, 535 (1981).

The United States Supreme COurt held that "deliberate indifference to serious medical needs" of convicted prisoners violates the proscription of cruel and unusual punishment stated in the Eighth Amendment to the United States Constitution. Estelle v. Gamble, 429 U.S. 97 (1976).

The Supreme Court stated that § 1983 "creates a species of tort liability," Imbler v. Pachtman, 424 U.S. 408 (1976) and that sctions under the statute sre governed by common law tort principles. See Cary v. Piphus, 435 U.S. 247, 257-259 (1978). A showing of proximate cause is a necessary elememt in a § 1983 action, See Daniels v. Gilbreath, 668 F.2d 1350,1355 (9th Cir. 1985), and that causation is ordinnarily for the jury Zezuski v. Jenny Mfg. Co., 363 Mass. 324,328 (1973). "A plaintiff

need only show 'that there was greater likelihood or probability that the harm complained of was due to causes for which the defendant was responsible than any other cause.'" Mullins v. Pine Manoe College, 389 Mass. 47,58 (1983). It must be shown how ever, that a defendant's negligent conduct is a "substantial factor" in bringing about the harm to the plaintiff. Restatement (Second) of Torts § 431 (1965).

The plaintiff has already established essential elements of his claim "either by direct evidence or rational inference of probabilities from established facts." [411 Mass. 92] Zezuski v. Jenny Mfg. Co., by a showing of the medical records which verify the Plaintiff's steady weight loss without receiving treatment for over one year for it, and by the physicians notes verifying that Plaintiff is in need of special footware and none was ordered, and that percosets were given to the Plaintiff for six months when oxicodone was prescribed and that methadone was prescribed to try to correct the neglegent medical order. The Plaintiff can also show that the defendants are acting in a retalitory manner by eliminating all pain medication to date. The Plaintiff's likelihood of success on the merits are strong once all the discovery process is completed, and the Plaintiff will also be able to show a blatent and continual neglect on the part of the defendants toward all inmates medical needs. The medical records, when viewed in light most favorable to the plaintiff will show his success is inevitable.

For the reasons stated herein and the case law supporting the Plaintiff's claims he is likely to prevail on his claims for success on the merits and should therefore be granted an immediate Restraining Order against the defendants restraining them from harming him any further and correcting the immediate medical needs of the plaintiff.

Rather, because plaintiff's request for a TRO was denied, and because he filed a grievance about experiencing withdrawal symptoms, defendants are acting in retaliation against the Plaintiff for exerting his civil rights to proper medical care.

Plaintiff requests an immediate hearing on the issues for an injunction or in the alternative a Temporary Restraining Order before the withdrawal symptoms put the plaintiff's health at further jeapordy.

WHEREFORE, for the foregoing reasons, the Plaintiff respectfully requests this Motion for a Temporary Restraining Order be allowed.

I hereby certify that a true copy of the above document was served upon each party, attorney of record by mail this 7th day of April 2005.

Lloyd F. Audette

Lloyd F. Audette

Respectfully submitted,
By the Plaintiff, pro-se

Lloyd F. Audette

Lloyd F. Audette
S.B.C.C./P.O. Box 8000
Shirley MA 01464

EXHIBIT

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.: 05-10403DPW

LLOYD F. AUDETTE,
Plaintiff,

V.

UMASS CORRECTIONAL HEALTH,
A Commonwealth Medicine Program,
Defendant, and

DEPARTMENT OF CORRECTON
Kathleen M. Denney, Commissioner,
Defendant.

AFFIDAVIT OF JAMES A. BELLO

I, James A. Bello, being duly sworn, hereby depose and state the following:

1. I am a partner at the law firm of Morrison Mahoney, with offices located at 250 Summer Street, Boston, Massachusetts 02210. I am duly licensed to practice law and I am in good standing in the Commonwealth of Massachusetts.

2. I am counsel for defendant, UMASS Correctional Health ("UMCH"), in the above referenced matter. I have personal knowledge of all facts set forth herein and I am familiar with plaintiff's allegations and the procedural history of this case.

3. I spoke with Health Service Administrator for the Souza-Baranowski Correctional Center ("SBCC"), Charlie Black, on March 25, 2005. During this telephone conversation, we discussed the status of plaintiff, Lloyd Audette's, medical treatment. Specifically, Mr. Black addressed the five requests included in plaintiff's Motion for a Temporary Ex Parte Restraining Order.

5. Regarding plaintiff's first request, Mr. Black told me that a podiatrist, Dr. King, recommended plaintiff wear Rockport walking shoes to help remedy his bone spur. Mr. Black noted that Dr. King never filled out a physician's order, requesting that the Department of Correction ("DOC") pay for these shoes. In response to the doctor's recommendation, Mr. Black ordered the Rockport walking shoes for the DOC Canteen. These shoes are now available at the Canteen for plaintiff's purchase at his discretion.

6. When addressing plaintiff's second request, Mr. Black pointed out that Dr. Stone, the infectious disease specialist at the SBCC, had concerns about treating Mr. Audette with testosterone injections, given his history of HIV and Hepatitis C. Mr. Black informed me that plaintiff Audette was not receiving testosterone upon his arrival at SBCC, in February of 2004. Nevertheless, defendants still scheduled an appointment with the endocrinologist for the near future, so that plaintiff can be evaluated for testosterone therapy.

7, Mr. Black also noted that when plaintiff meets with the endocrinologist, his third request, for Oxandorlone medication, will also be discussed. Mr. Black informed me that even though Audette never requested this medication from the SBCC, UMCH will still consult with the endocrinologist as to the effectiveness of this type of anabolic steroid treatment.

8. Mr. Black and I also discussed plaintiff's fifth request for an increase in his methadose medication. Mr. Black mentioned that Dr. Stone expressed concern for plaintiff's health, given that Mr. Audette also receives Sustiva and DDI medication for his Hepatitis C. Specifically, Dr. Stone noted that literature warns of declined efficacy in the Hepatitis C drugs if the level of methadose is too high. Wary about offsetting the

balance in plaintiff's medical treatments, Mr. Black told me that on April 4, 2005, plaintiff will be seen in the Infectious Disease Clinic at which point the issue will be addressed. not done to date April 7, 2005

9. The above statements are true and accurate and based upon my personal knowledge.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY

THIS 25 DAY OF MARCH, 2005.

James A. Bello (BBO# 633550)

AFFIDAVIT

I Russ Michael Dagenais, do hereby depose and say that the foregoing statements are true and accurate to the best of my knowledgs and recollection.

1. My name is Russ Michael Dagenais.

2. I am an inmate housed at the Souza Baronowski Correctional Center and was housed there on the date in question.

3. That on or about the week of February 18, 2005, I witnessed inmate Lloyd Audette argueing with the kitchen lieutenent Sid Johnson because he did not receive an A.M. snack.

4. I witnessed Lt. Sid Johnson refuse to give inmate Audette an A.M. snack and after inmate Audette walked away from diet window I heard Lt. Sid Johnson laugh and state to the other officers, "I don't care what the order states, I don't think he needs a snack and I'm not going to give him one."

5. That the table I sit at in the chow hall is only a few feet away from the diet window and I can both clearly see and hear with clarity everything that was said at the diet window.

6. I also witnessed inmate Audette try to give Lt. Sid Johnson a copy of the diet order he took out of his pocket and Lt. Sid Johnson refused to accept it while stating, "Have it faxed to me."

7. Inmate Audette then stated that he had medical fax the order to him four times that week and then Lt. Sid Johnson stated, "Well, I guess that I don't have a fax machine."

8. There were other occassions that I witnessed similar events take place between inmate Audette and Lt. Sid Johnson but I don't recall the exact dates or words involved, but it always stemmed from inmate Audette being refused an A.M. snack from the kitchen.

9. From what I observed, it seemed to be an on going problem between inmate Audette and the kitchen lieutenent Sid Johnson in not providing inmate Audette with dietary snacks.

Signed under the penalties of perjury on this the 19TH day of MARCH, 2005.

Russ M. Dagenais

UMASS CORRECTIONAL HEALTH
A Commonwealth Medicine Program

Inmate Grievance and Appeal Form

Facility:

Grievance ☐ Date:

Inmate First Name: ID#:

Appeal ☐ Date:

Inmate Last Name: Date of Birth: Housing Unit:

Summary of Grievance or Reason for Appeal (Attach Additional Sheets As Necessary):

I spoke to Mindy the INfectious Desease nurse more than once and also showed her literature verifying that one of the HIV medications I am on, SUSTIVA, has a blocker in it that stops methadone from absorbing into my bloodstream and that I have been getting no effect from the methadone and am experiencing withdrawals from it every day. She told me she spoke to Dr. Hazard and she too agrees that sustiva does this but the problem was not resolved. I am either deemed to suffer in pain and withdrawals or stop taking my HIV medication. This is unacceptable. I still have not gotten any results regarding the weight loss problem that has been goin on for one year to date. I have lost a total of 45 pounds and still have not been evaluated for testosterone treatment as I was receiving on the street. I am also filing a complaint with the Board of Registration of Medicine as well as sending a copy of this grievance to the COmmissioner and to the Clerk of Court.

Remedy Requested (Attach Additional Sheets As Necessary):

Correct this problem**TODAY, TOMORROW IS UNACCEPTABLE!!!**

Inmate Signature:	Date:
Lloyd Coulter	March 28 2005

- **Completed forms may be filed with the HSA/DON/MHD or placing the form in the Sick Call Box. For inmates in special management units, forms may be handed to rounding HSU staff.**
- **An inmate may appeal the decision of the HSA/DON/MHD to the UMCH Medical Director.**
- **An appeal must be filed within ten (10) working days from the receipt of the decision by the HSA.**
- **Appeals should be filed with the HSA. For inmates in special management units, forms may be handed to rounding HSU staff.**
- **An inmate may file the appeal directly with the UMCH Medical Director, by sending it to**
  Medical Director
  UMass Correctional Health
  One Research Drive—Suite 120C
  Westborough, MA 01581

Health Services Unit Use ONLY:

Date Received:		Staff Recipient:		Routed To:	

cc. Katheleen M. Dennehy
Clerk Federal Court/ Audette v. UMASS et al No. 05-10404-DPW

[redacted]

Evidence

[redacted]

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Twice daily subcutaneous injections from single-use vials.	Serious allergic reactions, such as trouble breathing, fever with vomiting and a skin rash, blood in urine, and swelling of feet. Also local skin reactions at the site of injection.	Watch for symptoms of bacterial pneumonia, such as cough with fever, rapid breathing, and shortness of breath. Consult a physician immediately if signs of a serious allergic reaction or pneumonia develop. Also watch for infection at site of injections.

[redacted]

DRUG NAMES & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	400 mg (either four 100 mg or two 200 mg tablets) three times a day.	Rash (indicating life-threatening Stevens-Johnson syndrome in rare cases). If rash develops, contact physician.	Take with cranberry or orange juice if you have low stomach acid. Benadryl or topical corticosteroids may relieve rash symptoms. One study shows women may have higher blood levels of Rescriptor.
	One 600 mg tablet a day. For ages 3 and up.	Light-headedness, sleeplessness, dizziness, body ache, rash, headache, diarrhea, nausea, elevated liver enzymes. Vivid dreams often associated.	If a problem, take before bedtime to avoid nervous system side effects and light-headedness. Drug penetrates blood-brain barrier. Warning: not for use in pregnancy. Take on an empty stomach.
	One 200 mg tablet twice a day.	Fever, muscle soreness, elevated liver function, rash (possibly indicating life-threatening Stevens-Johnson syndrome in rare cases).	If rash develops, call your doctor; Benadryl or topical corticosteroids may relieve rash symptoms. Drug crosses the placenta. Take with or without food. Monitor liver functions closely during first 12 weeks.

[redacted]

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Two tablets a day.	See Epivir (3TC) and Retrovir (AZT).	Watch for anemia and myopathy (muscle pain). Also associated with bone marrow problems.
	One 200 mg a day.	Headache, diarrhea, nausea, rash.	Take with or without food. Reduction of dosage is recommended for patients with impaired kidney function.
	One 300 mg a day or two 150 mg/day.	Headache, nausea, fatigue, low white-blood-cell count, congestion, runny nose, hair loss (rare), neuropathy.	Watch for anemia. Monitor triglycerides for pancreatitis, especially in children. Take with or without food. Synergistic antiviral effect reported when combined with Crixivan and AZT.
	One tablet once a day.	Headache, nausea, fatigue, low white-blood-cell count, neuropathy, rare allergy, abdominal pain, and gastrointestinal and liver problems.	Watch for hypersensitivity reaction associated with abacavir-containing medications. Should not be used by patients who have exhibited symptoms of hypersensitivty to abacavir. No food restrictions.
	One 0.75 mg tablet every eight hours.	Skin rashes, canker sores, inflammation of mouth, nausea, neuropathy, upset stomach, pancreatitis, liver damage.	Avoid taking with food if possible.
[redacted]	600 mg a day (two 300 mg tablets or six 100 mg capsules).	Nausea, vomiting, anemia, low white-blood-cell counts, bone marrow damage, headaches, rash, itching, weakness, loss of appetite.	Best on empty stomach; take AZT with food if you have stomach irritation. Watch for anemia and neutropenia. Warning: A structural flaw in AZT may lead to HIV resistance. No food restrictions.
[redacted]	One capsule twice a day.	See Epivir (3TC), Retrovir (AZT), and Ziagen (abacavir).	Should not be prescribed for anyone who weighs less than 88 pounds or other patients requiring dose adjustments. Permanently discontinue if hypersensitivity to abacavir cannot be ruled out after the onset of the common side effects. No food restrictions.
[redacted]	One capsule once a day.	Granted accelerated approval by FDA; final safety and efficacy studies are ongoing.	Existing data from the use of Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine) have been extrapolated for current recommendations and warnings. [CONTINUES]

Evidence

NUCLEOSIDE/NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTIs)

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Patients weighing ≥60 kg (132 lbs) take one 400 mg once a day; <60 kg take one 250 mg once a day.	Stomach pain, diarrhea, pancreatitis, hepatitis, seizures, headaches; neuropathy with high doses.	Avoid alcohol, which increases risk of pancreatitis. Take on empty stomach at least 30 minutes before meal. Increased risk of pancreatitis with d4T and possibly hydroxyurea.
	One 300 mg tablet a day.	Elevated creatine phosphoskinase and transaminases. Diarrhea, nausea, vomiting. Possible bone toxicity.	This medication is a nucleotide reverse transcriptase inhibitor. Watch for lactic acidosis and hepatomegaly with steatosis (severe liver enlargement and excess fat in the liver). No food restrictions.
	Patients weighing ≥60 kg (132 lbs) take one 40 mg twice a day; <60 kg take one 30 mg twice a day.	Neuropathy, pancreatitis, insomnia, hyperactivity, elevated liver enzymes, and anemia at high doses.	Watch for neuropathy and pancreatitis. Watch for signs of lactic acidosis; permanent discontinuation should be considered in confirmed cases. No food restrictions.
	One 300 mg tablet twice a day.	Headache, fatigue, rare allergy (fever, rash, nausea, dizziness, vomiting), abdominal pain, and gastrointestinal and liver problems. Allergy may be signs of serious hypersensitivity.	Stop drug immediately if any sign of allergy occurs. Do not resume treatment after reaction; fatal reactions have been reported after treatment was resumed. Avoid during pregnancy. Abacavir Hypersensitivity Registry has been established: (800) 270-0425. No food restrictions.

[redacted]

DRUG NAME & MAKER	SUGGESTED DOSAGE	KNOWN SIDE EFFECTS	RECOMMENDATIONS & WARNINGS
[redacted]	Eight 150 mg capsules twice a day.	Nausea, gas, headache, neuropathy, rash, diarrhea, mouth numbing, fatigue. Rare: Stevens-Johnson syndrome.	Contains high levels of vitamin E. Consult with your doctor about possible interactions with vitamin E supplements or blood-thinning drugs. Take with or without food but avoid high-fat meals.
	Two 400 mg capsules every eight hours.	Kidney stones, anemia; rarely elevates liver enzymes. May increase risk of thrombosis. In rare instances, hair loss.	Take on empty stomach with water one hour before or two hours after eating. Drink at least six glasses of water daily to avoid kidney stones or consider lower dose with Norvir. Alternative liquids: juice (except grapefruit), skim milk, coffee, tea. Take with fat-free snacks.
	1,200 mg (one 400 mg and one 800 mg) boosted with 100 mg Norvir three times a day.	Diarrhea, gas, nausea, stomach cramps, heartburn, fatigue, numbness, rash, elevated liver enzymes.	Take with food or within two hours of eating. Fortovase is more potent than Invirase. Invirase not recommended as first-line therapy due to poor absorption and resistance issues.
	1,000 mg (two 500 mg tablets) boosted with one 100 mg ritonavir twice daily.	Abdominal discomfort, diarrhea, dizziness, numbness, rash. Spontaneous bleeding has occurred in patients with hepatitis A and B.	Not suggested for patients with liver problems. Take within two hours after a meal. Use of garlic capsules can reduce concentrations in the blood.
	Three (400 mg lopinavir/100 mg ritonavir coformulated) twice a day.	Nausea, skin rash, diarrhea, loose stools, elevated triglyceride and lipid levels, fatigue, and pancreatitis.	Do not take with Rescriptor or additional Norvir. Take with food.
	One 700 mg with one 100 mg of ritonavir twice a day. Or two 700 mg twice a day for protease-inhibitor–naive patients	Diarrhea, nausea, vomiting, headache, and rash.	Once daily dosing with ritonavir is not recommended for protease-inhibitor–experienced patients. Take with or without food or water. Three alternate dosing recommendations for protease-inhibitor–naive patients is available.
	One 600 mg twice a day.	Nausea, vomiting, weakness, diarrhea, rash, fatigue, numbness around mouth, changed taste in mouth, elevated liver enzymes.	Build up to optimal dose over a few days. Take with a full, high-protein meal. Yogurt may reduce side effects. Separate ddI dosing by at least two hours.
	Two 200 mg capsules once a day.	Nausea, infection, headache, vomiting, diarrhea, abdominal pain, drowsiness, insomnia, and fever.	Take with food. Watch for hyperbilirubinemia (abnormally high amounts of an orange-yellow pigment in the bile) in the blood.
	Five 250 mg two times/day or two 625 mg two times/day.	Fatigue, rash, nausea, stomach cramps, diarrhea, elevated liver enzymes.	Take with food. Use Imodium or Lomotil to control diarrhea. Dose desensitization can work for patients experiencing rash.

[redacted] This side Evidence

PATIENT INFORMATION

℞ ONLY

SUSTIVA® (sus-TEE-vah) [efavirenz (eh-FAH-vih-rehnz)] capsules and tablets

ALERT: Find out about medicines that should NOT be taken with SUSTIVA.

Please also read the section **"MEDICINES YOU SHOULD NOT TAKE WITH SUSTIVA."**

Read this information before you start taking SUSTIVA (efavirenz). Read it again each time you refill your prescription, in case there is any new information. This leaflet provides a summary about SUSTIVA and does not include everything there is to know about your medicine. This information is not meant to take the place of talking with your doctor.

What is SUSTIVA?

SUSTIVA is a medicine used in combination with other medicines to help treat infection with Human Immunodeficiency Virus type 1 (HIV-1), the virus that causes AIDS (acquired immune deficiency syndrome). SUSTIVA is a type of anti-HIV drug called a "non-nucleoside reverse transcriptase inhibitor" (NNRTI). NNRTIs are not used in the treatment of Human Immunodeficiency Virus type 2 (HIV-2) infection.

SUSTIVA works by lowering the amount of HIV-1 in the blood (viral load). SUSTIVA must be taken with other anti-HIV medicines. When taken with other anti-HIV medicines, SUSTIVA has been shown to reduce viral load and increase the number of CD4+ cells, a type of immune cell in blood. SUSTIVA may not have these effects in every patient.

SUSTIVA does not cure HIV or AIDS. People taking SUSTIVA may still develop other infections and complications. Therefore, it is very important that you stay under the care of your doctor.

SUSTIVA has not been shown to reduce the risk of passing HIV to others. Therefore, continue to practice safe sex, and do not use or share dirty needles.

What are the possible side effects of SUSTIVA?

Serious psychiatric problems. A small number of patients experience severe depression, strange thoughts, or angry behavior while taking SUSTIVA. Some patients have thoughts of suicide and a few have actually committed suicide. These problems tend to occur more often in patients who have had mental illness. Contact your doctor right away if you think you are having these psychiatric symptoms, so your doctor can decide if you should continue to take SUSTIVA.

Common side effects. Many patients have dizziness, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with SUSTIVA. These side effects may be reduced if you take SUSTIVA at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. If you have these common side effects, such as dizziness, it does not mean that you will also have serious psychiatric problems, such as severe depression, strange thoughts, or angry behavior. Tell your doctor right away if any of these side effects continue or if they bother you. It is possible that these symptoms may be more severe if SUSTIVA is used with alcohol or mood altering (street) drugs.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Rash is common. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your doctor right away. **Rash may be a serious problem in some children.** Tell your child's doctor right away if you notice rash or any other side effects while your child is taking SUSTIVA.

Other common side effects include tiredness, upset stomach, vomiting, and diarrhea.

Changes in body fat. Changes in body fat develop in some patients taking anti-HIV medicine. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these fat changes are not known.

Tell your doctor or healthcare provider if you notice any side effects while taking SUSTIVA.

Contact your doctor before stopping SUSTIVA because of side effects or for any other reason.

This is not a complete list of side effects possible with SUSTIVA. Ask your doctor or pharmacist for a more complete list of side effects of SUSTIVA and all the medicines you will take.

How should I take SUSTIVA?

General Information

- You should take SUSTIVA on an empty stomach, preferably at bedtime.
- Swallow SUSTIVA with water.
- Taking SUSTIVA (efavirenz) with food increases the amount of medicine in your body, which may increase the frequency of side effects.
- Taking SUSTIVA at bedtime may make some side effects less bothersome.
- SUSTIVA must be taken in combination with other anti-HIV medicines. If you take only SUSTIVA, the medicine may stop working.
- Do not miss a dose of SUSTIVA. If you forget to take SUSTIVA, take the missed dose right away, unless it is almost time for your next dose. Do not double the next dose. Carry on with your regular dosing schedule. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.
- Take the exact amount of SUSTIVA your doctor prescribes. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop.
- If you believe you took more than the prescribed amount of SUSTIVA, contact your local Poison Control Center or emergency room right away.
- Tell your doctor if you start any new medicine or change how you take old ones. Your doses may need adjustment.
- When your SUSTIVA supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to SUSTIVA and become harder to treat.
- Your doctor may want to do blood tests to check for certain side effects while you take SUSTIVA.

Capsules

- The dose of SUSTIVA capsules for adults is 600 mg (three 200-mg capsules, taken together) once a day by mouth. The dose of SUSTIVA for children may be lower (see **Can children take SUSTIVA?**).

Tablets

- The dose of SUSTIVA tablets for adults is 600 mg (one tablet) once a day by mouth.

Can children take SUSTIVA?

Yes, children who are able to swallow capsules can take SUSTIVA. Rash may be a serious problem in some children. Tell your child's doctor right away if you notice rash or any other side effects while your child is taking SUSTIVA. The dose of SUSTIVA for children may be lower than the dose for adults. Capsules containing lower doses of SUSTIVA are available. Your child's doctor will determine the right dose based on your child's weight.

Who should not take SUSTIVA?

Do not take SUSTIVA if you are allergic to the active ingredient, efavirenz, or to any of the inactive ingredients. Your doctor and pharmacist have a list of the inactive ingredients.

What should I avoid while taking SUSTIVA?

- **Women taking SUSTIVA should not become pregnant.** Serious birth defects have been seen in the offspring of animals and women treated with SUSTIVA during pregnancy. It is not known whether SUSTIVA caused these defects. **Tell your doctor right away if you are pregnant.** Also talk with your doctor if you want to become pregnant.
- Women should not rely only on hormone-based birth control, such as pills, injections, or implants, because SUSTIVA may make these contraceptives ineffective. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control.
- **Do not breast-feed if you are taking SUSTIVA.** The Centers for Disease Control and Prevention recommend that mothers with HIV not breast-feed because they can pass the HIV through their milk to the baby. Also, SUSTIVA may pass through breast milk and cause serious harm to the baby. Talk with your doctor if you are breast-feeding. You may need to stop breast-feeding or use a different medicine.
- Taking SUSTIVA with alcohol or other medicines causing similar side effects as SUSTIVA, such as drowsiness, may increase those side effects.
- Do not take any other medicines without checking with your doctor. These medicines include prescription and nonprescription medicines and herbal products, especially St. John's wort.

Before using SUSTIVA, tell your doctor if you

- **have problems with your liver or have hepatitis.** Your doctor may want to do tests to check your liver while you take SUSTIVA.
- **have ever had mental illness or are using drugs or alcohol.**
- **have ever had seizures or are taking medicine for seizures** [for example, Dilantin® (phenytoin), Tegretol® (carbamazepine), or phenobarbital]. Your doctor may want to check drug levels in your blood from time to time.

What important information should I know about taking other medicines with SUSTIVA?

SUSTIVA (efavirenz) may change the effect of other medicines, including ones for HIV, and cause serious side effects. Your doctor may change your other medicines or change their doses. Other medicines, including herbal products, may affect SUSTIVA. For this reason, **it is very important to:**

- let all your doctors and pharmacists know that you take SUSTIVA.
- tell your doctors and pharmacists about all medicines you take. This includes those you buy over-the-counter and herbal or natural remedies.

Bring all your prescription and nonprescription medicines as well as any herbal remedies that you are taking when you see a doctor, or make a list of their names, how much you take, and how often you take them. This will give your doctor a complete picture of the medicines you use. Then he or she can decide the best approach for your situation.

Taking SUSTIVA with St. John's wort *(Hypericum perforatum)*, an herbal product sold as a dietary supplement, or products containing St. John's wort is not recommended. Talk with your doctor if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease SUSTIVA levels and lead to increased viral load and possible resistance to SUSTIVA or cross-resistance to other anti-HIV drugs.

MEDICINES YOU SHOULD NOT TAKE WITH SUSTIVA

The following medicines may cause serious and life-threatening side effects when taken with SUSTIVA. You should not take any of these medicines while taking SUSTIVA:

- Hismanal® (astemizole)
- Propulsid® (cisapride)
- Versed® (midazolam)
- Halcion® (triazolam)
- Ergot medications (for example, Wigraine® and Cafergot®)

The following medicine should not be taken with SUSTIVA since it may lose its effect or may increase the chance of having side effects from SUSTIVA:

- Vfend® (voriconazole)

The following medicines may need to be replaced with another medicine when taken with SUSTIVA (efavirenz):

- Fortovase®, Invirase® (saquinavir)
- Biaxin® (clarithromycin)

The following medicines may need to have their dose changed when taken with SUSTIVA:

- Crixivan® (indinavir)
- Kaletra® (lopinavir/ritonavir)
- Methadone
- Mycobutin® (rifabutin)
- REYATAZ® (atazanavir sulfate). If you are taking SUSTIVA and REYATAZ, you should also be taking Norvir® (ritonavir).
- Zoloft® (sertraline)

These are not all the medicines that may cause problems if you take SUSTIVA. Be sure to tell your doctor about all medicines that you take.

General advice about SUSTIVA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use SUSTIVA for a condition for which it was not prescribed. Do not give SUSTIVA to other people, even if they have the same symptoms you have. It may harm them.

Keep SUSTIVA at room temperature (77°F) in the bottle given to you by your pharmacist. The temperature can range from 59° to 86°F.

Keep SUSTIVA out of the reach of children.

This leaflet summarizes the most important information about SUSTIVA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for the full prescribing information about SUSTIVA, or you can visit the SUSTIVA website at http://www.sustiva.com or call 1-800-426-7644.

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Evidence

INBRIEF

Viramune Can Affect Methadone Use

Adults who are HIV-positive and take an antiretroviral cocktail containing Viramune and who also are on methadone therapy to treat drug addiction might have to have their methadone doses increased because of interactions between the medications, researchers in Germany report.

The scientists examined 20 HIV patients taking both Viramune and methadone and discovered that among some of the study subjects methadone absorption into the bloodstream was severely suppressed. Blood-based methadone levels fell by an average of 29%, but absorption of the drug dropped as much as 70% in some HIV patients. All but six patients required higher methadone doses to prevent drug-withdrawal symptoms.

Because blood-based levels of Viramune were unaffected, the researchers say the medications can be prescribed together as long as methadone doses are adjusted as needed for full efficacy.

Alcohol Increases Oral Infection Risk

Exposing cells from the mouth to alcohol—even at concentrations similar to those in beer and wine—can make them more suspectible to HIV infection, according to a study in the December 1 issue of *Journal of Acquired Immune Deficiency Syndromes.*

Researchers at the University of California, Los Angeles, Dental Institute exposed oral epithelial cells from HIV-negative adults to various concentrations of ethanol, then exposed them to a strain of HIV engineered to be easily detectable. Cells exposed to a 4% alcohol solution—similar to the concentration in beer—for 10 minutes showed a three-fold to six-fold greater susceptibility to infection than unexposed cells. Further analysis showed the boosted infection risk was linked directly to alcohol's effect on the cells and not on the virus.

The researchers say they are unclear how HIV entered the cells, since they lack a key receptor necessary for HIV attachment. They theorize, though, that alcohol either alters the cellular membranes to allow viral entry or interacts with key proteins to enable cellular fusion and infection.

SAN FRANCISCO AND BEER IMAGES FROM PHOTOS.COM

Evidence

Can Liver Damage Lead to Diabetes?

Liver damage, as measured by abnormal levels of the liver enzyme ALT, might boost the risk for type II diabetes among HIV-positive adults, U.S. researchers note in the December 1 issue of *Journal of Acquired Immune Deficiency Syndromes*.

High body weight relative to height and genetic factors—including having diabetic relatives—also were linked with the development of the disease.

The researchers studied the records of HIV patients receiving care between 1991 and 2000 at two New York clinics. They discovered that patients who developed diabetes had significantly higher ALT levels than those who did not during the course of the study.

Doctors should closely monitor HIV patients with elevated liver enzyme levels for early signs of the onset of diabetes, the researchers conclude. Careful monitoring also should be given to overweight patients and those with a family history of the disease.

LIVER IMAGE BY JOHN M. DAUGHERTY/PHOTO RESEARCHERS INC.; CONDOMS FROM MEWSCOM

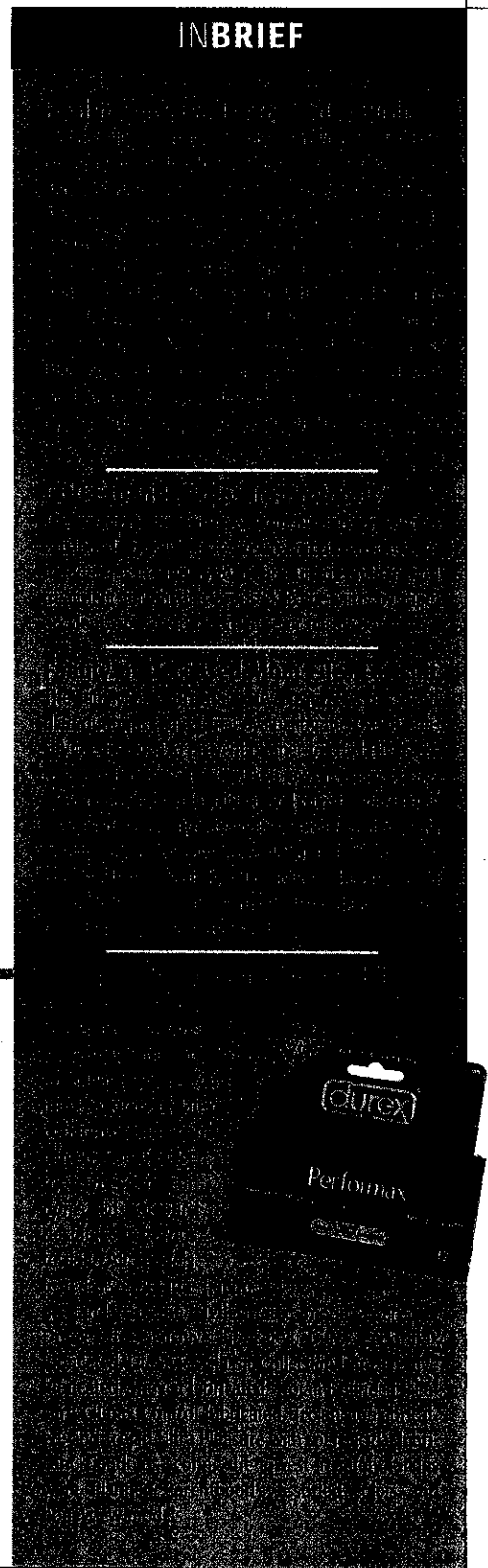
Weight Loss Is Linked to CD4 Counts

HIV-related weight loss is linked to decreasing CD4-cell counts—not to HIV viral levels—in adults taking antiretroviral drugs, according to the U.S. Nutrition for Healthy Living Study. Data from the study published in the January 1 issue of *Clinical Infectious Diseases* show that for HIV-positive adults on a successful and stable antiretroviral regimen, changes in CD4-cell counts are associated with changes in weight.

Researchers report that a CD4-cell-count drop of 100 was linked with an average weight loss of 0.35 kilogram—slightly less than one pound.

The link between CD4-cell levels and weight loss suggests that controlling viral load is not enough to prevent weight changes in HIV-positive adults taking anti-HIV drugs, the researchers conclude. Changing anti-HIV drugs to a regimen that both controls viral replication and leads to CD4-cell rebounds could help avoid the onset of HIV-related wasting or lead to a regaining of lost weight, they say.

INBRIEF



CD4 dropped to 137 because of low testosterone levels

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